APR - 8 2011

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K101744

Company/Contact person

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Date Prepared

May 15, 2010

Regulatory Declarations

Common / Usual Name	CEDIA® Cannabinoids OFT Assay CEDIA® THC OFT Calibrators
Trade/ Proprietary Name	Thermo CEDIA® Cannabinoids OFT Assay Thermo CEDIA® THC OFT Calibrators
Classification Regulation	21 CFR 862.3870 21 CFR 862.3200
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	LDJ, DLJ

Intended use

The CEDIA® Cannabinoids OFT Assay is intended for use in the qualitative determination of Cannabinoids in human oral fluid at a cutoff concentration of 3 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against *l*-Δ^9 THC and performed on the MGC 240. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The CEDIA THC OFT Calibrators are intended for use in the calibration of *l*-Δ^9 THC when used with the CEDIA Cannabinoids OFT Assay. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The CEDIA Cannabinoids OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.

Conditions for use

The CEDIA® Cannabinoids OFT Assay is for prescription professional use only in clinical chemistry laboratories. It is not for use in Point of Care settings.

Legally marketed device to which equivalency is claimed

CEDIA® Cannabinoids OFT Assay is substantially equivalent to the previously cleared STC Cannabinoids Intercept® MICRO-PLATE EIA, K002375 (At present OTI, OraSure Technologies Inc.)

DESCRIPTION OF DEVICE

CEDIA® Cannabinoids OFT Assay

Microgenics CEDIA® Cannabinoids OFT Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously re-associate to form fully active enzyme that, in the assay format, cleave a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment (enzyme donor) of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragment free to form active enzyme. If the analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the re-association of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of analyte present in the sample.

Principle of Oral-Eze™ Saliva Collection System

The Oral-Eze™ Saliva Collection System consists of Oral-Eze™ saliva collector and collection tube with preservative buffer. Oral-Eze™ saliva collector consists of an absorbent pad attached to a plastic handle. The saliva collector is provided with a volume adequacy indicator. The plastic handle has a round window where blue color will appear when sufficient volume of oral fluid is collected. Samples are collected by placing the collector pad and plastic shield between lower cheek and gum with the plastic shield facing the cheek. Oral fluid collection is done when blue color appears in the window of the handle. The pad is ejected in to the collection tube by placing thumb on the ridges on the handle and pushing the thumb forward. The collection tube is capped and sent to the laboratory for processing and testing.

Comparison of Technological Characteristics

CEDIA® Cannabinoids OFT Assay is compared below to the previously cleared STC Cannabinoids Intercept® MICRO-PLATE EIA, K002375 (At present OTI, OraSure Technologies Inc.)

Comparison	Subject Device CEDIA® Cannabinoids OFT Assay	Predicate Device OTI Cannabinoids Intercept® MICRO-PLATE EIA K002375
Intended Use	The CEDIA® Cannabinoids OFT Assay is intended for use in the qualitative determination of Cannabinoids in human oral fluid at a cutoff concentration of 3 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against *l*-Δ^9 THC and performed on the MGC 240. This *in vitro* diagnostic device is intended for clinical laboratory use only. The CEDIA THC OFT Calibrators are intended for use in the calibration of *l*-Δ^9 THC when used with the CEDIA Cannabinoids OFT Assay. This *in vitro* diagnostic device is intended for clinical laboratory use only. The CEDIA Cannabinoids OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.	The OTI Cannabinoids Intercept® MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of cannabinoids in oral fluid collected with the Intercept® Drugs of Abuse (DOA) Oral Specimen Collection Device. For In Vitro Diagnostic Use. The OTI Cannabinoids Intercept® MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. This is a confirmation method that is currently pending SAMHSA acceptance. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.
Test Principle	Microgenics CEDIA® Cannabinoids OFT Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments	The OTI Cannabinoids Intercept® MICRO-PLATE EIA is a competitive immunoassay for the detection of cannabinoids in oral fluid collected with the Intercept® DOA Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme-labeled hapten derivative.

	spontaneously re-associate to form fully active enzyme that, in the assay format, cleave a substrate, generating a color change that can be measured spectrophotometrically. In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment (enzyme donor) of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragment free to form active enzyme. If the analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the re-association of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of analyte present in the sample.	In an EIA well containing an oral fluid specimen positive for cannabinoids, there is a competition between the drug and the enzyme labeled hapten to bind the antibody fixed on the EIA well. EIA wells are then washed, substrate is added, and color is produced. The absorbance measured for each well at 450 nm is inversely proportional to the amount of cannabinoids present in the specimen or calibrator/control.
Sample Matrix	Oral Fluid	Oral Fluid
Calibrator levels	0, 1.0, 10.0 ng/mL	0, 1.0 ng/mL
Cutoff level	3.0 ng/mL in neat oral fluid	1.0 ng/mL
Unassayed Control levels	0.5, 1.5 ng/mL	0.5, 2.0 ng/mL

SUMMARY OF CLINICAL TESTING

Qualitative Precision

All samples tested recovered accurately. Samples at levels below the cutoff read as negative and samples at levels above the cutoff read as positive.

Qualitative Cutoff Characterization

All samples tested recovered accurately, low control as negative and high control level as positive.

Interference

Results demonstrated that there was no significant interference from endogenous and exogenous substances in oral fluid at the tested concentrations and in samples adjusted to pH range of 5 to 9.

Specificity and Cross-Reactivity

Cross-reactivity to metabolites and structurally related compounds was tested in the assay. No significant cross-reactivity was observed with other structurally unrelated compounds.

Qualitative Method Comparison

The overall concordance between the CEDIA® Cannabinoids OFT Assay and GC/MS is 98.8%. The comparison of sample results by the CEDIA® Cannabinoids OFT Assay to GC/MS showed 97.6% sensitivity and 100.0% specificity.

Conclusion

As summarized, the CEDIA® Cannabinoids OFT Assay is substantially equivalent to the OTI Cannabinoids Intercept® MICRO-PLATE EIA. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993

Microgenics Corp.
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APR 0 8 2011

Re: k101744
Trade Name: Thermo Scientific CEDIA Cannabinoids OFT Assay and Thermo Scientific CEDIA THC OFT Calibrators
Regulation Number: 21 CFR 862.3870
Regulatory Class: Class II
Product Codes: LDJ, DLJ
Dated: March 10, 2011
Received: March 14, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101744

Device Name: CEDIA® Cannabinoids OFT Assay
CEDIA® THC OFT Calibrators

Indications for Use:

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Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101744